

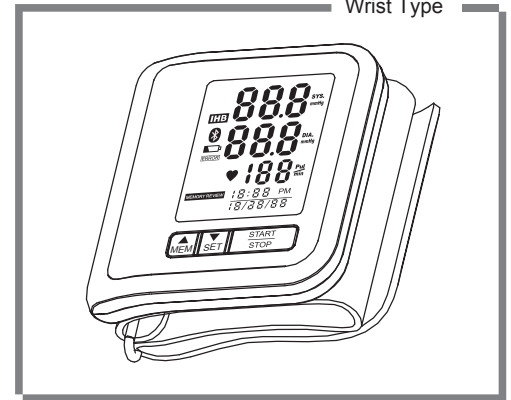
Version:1.0

SCIENCES
WWW.ICSCIENCES.COM

User Manual

Blood Pressure Monitor LS810-B

Wrist Type



- Thank you for selecting the IC Sciences Corporation Blood Pressure Monitor LS810-B.
- Please read this user manual carefully and thoroughly to ensure safe usage of this product. Keep this manual for further reference in case you have problems.



FCC ID: OU9LS810-B01

Distributed by:
Informed Clinical Sciences Corporation
1 Joy Street, Boston, USA MA 02108



Download and install My BP Coach
from iTunes Store or Google play



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♥ General Description

Thank you for selecting IC Sciences Corporation's Blood Pressure Monitor (LS810-B). The monitor features blood pressure measurement, pulse rate measurement and the data storage. The design provides you with two years of storage.

Readings taken by the LS810-B are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information and provides step-by-step instructions for using the product.

Please read this user manual carefully and thoroughly before use.

FEATURES:

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Pulse Rate
- Memory: Up to 60 records

♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a "zero point" equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate. The device also compares the longest and the shortest intervals of detected pulse wave with the average value, and then calculates the standard deviation. The monitor will light up a warning symbol when the calculated standard deviation is larger than or equal to 15.

♥ Safety Information

The below signs might be in the user manual, labeling or other components. They are the requirement of standard and using.

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
	Symbol for "Class II Equipment"		Symbol for "ENVIRONMENT PROTECTION - Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "MANUFACTURER"		Symbol for "DIRECT CURRENT"
SN	Symbol for "SERIAL NUMBER"		Symbol for "Including RF transmitter"
	The Bluetooth Combination Mark		
	Symbol for "MANUFACTURE DATE"		

♥ Indications for use

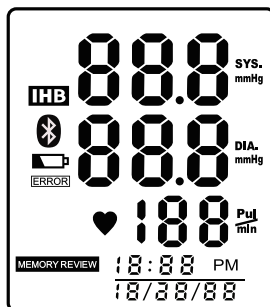
The IC Sciences Corporation Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5 cm to 21.5 cm (about 5-8.5 inches). It is intended for adult indoor use only.



CAUTION

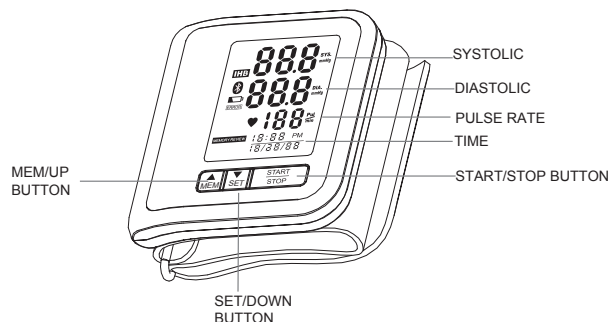
- * It is intended for adult indoor use only. Pregnant women, pre-eclamptic patients, and severely obese patients should not use the device. If you need to measure your blood pressure, please consult your physician.
- * This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.
- * Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Please start or end medical treatment basing solely on physician's treatment advice.
- * If you are taking medication, consult your physician to determine the most appropriate time for your measurement. Never change a prescribed medication without your physician's consent.
- * This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's wrist and fingers will become anaesthetic, swollen, and even purple due to a lack of blood.
- * If the pressure of the cuff exceeds 40 kPa (300 mmHg), the unit will automatically deflate. If the cuff doesn't deflate when its pressure exceeds 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
- * Do not use the monitor under the conditions of strong electromagnetic field (e.g. medical RF equipment) that radiates interference signal or electrical fast transient/ burst signal.
- * The maximum temperature that the applied part can be achieved is 42.5 °C (108.5 °F) while the environmental temperature is 40 °C (104 °F).
- * The device is not AP/AGP equipment. It is not suitable for use in the presence of a flammable anesthetic mixture with air (or oxygen, nitrous oxide).
- * Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
- * Please use ACCESSORIES and detachable parts specified / authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user / patient.
- * The patient is an intended operator. The patient can measure, transmit data and charge battery under normal circumstances and maintain the device and its accessories according to the user manual.
- * The blood pressure monitor, and the cuff are suitable for use within the patient environment. If you are allergic to dacton or plastic, please don't use this device.
- * The device is not intended for PATIENT transport outside a healthcare facility.
- * This device cannot be used with HF surgical equipment at the same time.
- * There is a PTC current limiter in the monitor, which specification is 8V and 0.5A. When the voltage and current exceed the limiting value, the monitor will stop working.
- * If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
- * Be careful of strangulation due to cables and hoses, particularly due to excessive length.

♥ LCD Display Signal



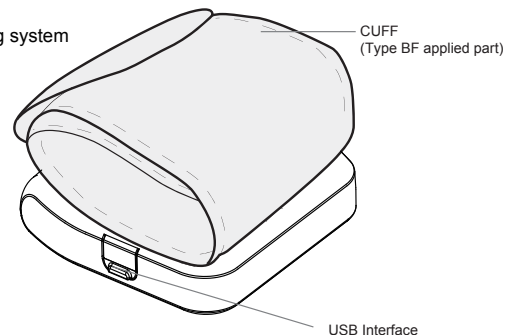
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	Top number in your blood pressure
DIA	Diastolic Blood Pressure	Bottom number in your blood pressure
Pul min	Pulse	beat/minute
+Lo	Low Battery	Low battery; please charge the power.
mmHg	Unit	Measurement unit of blood pressure
IHB	IHB Detector	Irregular Heartbeat Detector
Bluetooth	Bluetooth	Successful Bluetooth Connection
[ERROR]	Error	Error
MEMORY REVIEW	Memory	Recalling the history records
18:88 PM 18/88/88	Time	Hour:Minute (Month/Day/Year)
Heartbeat	Heartbeat	Heartbeat detection during the measurement

♥ Monitor Components



Component list of
pressure measuring system

- 1 PCBA
- 2 Air pipe
- 3 Pump
- 4 Valve
- 5 Cuff

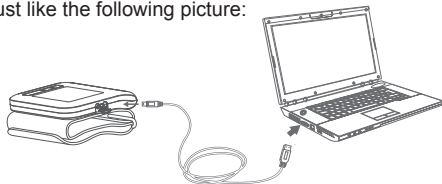


♥ List

1. Blood Pressure Monitor (LS810-B)
2. USB Cable
3. User Manual

♥ Power Supply and Charge Power

1. The battery of LS810-B is a built-in rechargeable lithium-ion battery, the battery current is 420 mAh.
2. Please use the USB cable to charge the battery, just like the following picture:



Charging the power under following circumstances:

- + displays on the LCD
- The LCD display dims
- When powering on the monitor, the LCD doesn't light up.

CAUTION

1. The battery of the LS810-B is a built-in rechargeable lithium-ion battery; please do not disassemble by unauthorized maintenance personnel.
2. Under normal use, it can be charged about 300 times.
If the battery cannot charge the power normally or the blood pressure monitor cannot be used normally, please connect with the authorized maintenance personnel. If measured three times per day, and the battery is fully charged, it can be used for about 20 days.
3. Store and use the blood pressure monitor in a cool, dry, and ventilated environment. Avoid close proximity to fire and extreme heat or it can cause the battery to explode.
4. You can only use the IC Science's authorized USB cable to charge the power. You cannot use the blood pressure monitor during charging.
5. During charging, the blood pressure monitor displays the symbol: When the charging is finished, please unplug the device.
6. When charging, do not touch the charging connector and the patient simultaneously.

♥ Download and install My BP Coach from iTunes Store or Google play

♥ Activate Your Blood Pressure Monitor

When you get the Blood Pressure Monitor, the first thing you must do is to activate it. Please press and hold the SET button to activate it, then it will enter the setting mode.

♥ Setting Date and Time

Please proceed to time setting before your initial use to ensure each piece of recorded information is labeled with a time stamp. (Year Range: 2012-2052; Time Format: 12 Hours)

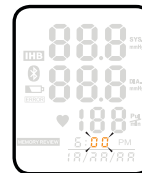
1. When the monitor is OFF, press and hold "SET" button for 3 seconds to enter Time Setting Mode.



2. As pictured in the right, the blinking numeral representing [HOUR]. Press "MEM" button to change the numeral. Each press will increase the numeral by one in a cycling manner.



3. Press "SET" button again to confirm [HOUR]. Then the numeral representing [MINUTE] blinks.



4. Repeat step 2 and 3 to confirm [MINUTE].



5. Repeat step 2 and 3 to confirm [MONTH], [DAY] and [YEAR].



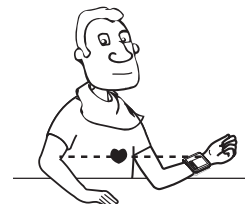
6. After confirming [YEAR], the LCD will display "dONE" and the monitor will shut off.





♥ Positioning the Cuff


1. Remove all accessories (watch, bracelet, etc) from your left wrist. If your physician has diagnosed you with poor circulation in your left wrist, use your right wrist.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your left wrist with your palm facing up.
4. Position the edge of the cuff about 1-2 cm (1 inch) from the bottom of the wrist.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
6. Patients with Hypertension:
The middle of the cuff should be at the level to the right atrium of the heart.
Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.


- Rest for 5 minutes before measuring your blood pressure.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as directed by a physician.



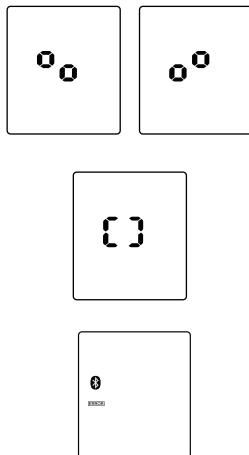
♥ Pair-up the Blood Pressure Monitor with Your Device

1. Turn on Bluetooth and the app.
Make sure both are ON when pair-up is proceeding.
2. When the monitor is OFF, press and hold the START button to start pair-up. The symbol  and the symbol  will be shown on the LCD alternatively, indicating pair-up is proceeding.

If **SUCCESSFUL**, symbol  will be shown on the LCD.


If **FAIL**, symbol  will be shown on the LCD.

3. The monitor will shut off after Pair-up process is complete.



Bluetooth Module No.: AW2540MV1
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: -1 dBm
Supply Voltage: 2 V to 3.6 V
Transmitting Distance: 10 meters

CAUTION

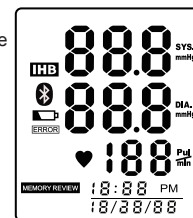
- Interference may occur in the vicinity of equipment marked with the following symbol . And LS810-B may interfere in the vicinity of electrical equipment.
- Keep the monitor at least 20 centimeters (8 inches) away from the human body (especially the head) when the data transmission is proceeding after measurement.
- To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

How to mitigate possible interference?

1. The range between the device and BT end should be reasonably close, from 1 meter to 10 meters (from 3 ft to 32 ft). Please ensure there are no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.
2. To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter (3 ft) away from the monitor.

♥ Start Measurement

1. After correctly positioning the cuff, press the START button to turn on the monitor, and it will complete the measurement process.



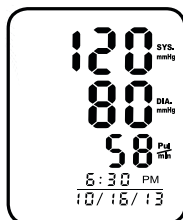
START
STOP

Adjust to zero.**Inflating and measuring.**

2. This device will proceed to transmit data after measurement.

The Bluetooth symbol blinking on the LCD indicates data is transmitting.

3. If the data is successfully transmitted, the LCD will then display "DONE".

Display and save the measuring result.

If the data transmission fails, the LCD will display "0" instead.

4. Press STOP button to turn off the monitor. Otherwise it will power off.



START
STOP

**CAUTION**

- When using this device, please pay attention to the following situations which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: too frequent and consecutive multiple measurements; the application of the CUFF and its pressurization on any wrist where intravascular, access or therapy, or an arterio-venous (A-V) shunt, is present; Inflating the cuff on the wrist on the side of a mastectomy.
- Do not apply the cuff over a wound, otherwise it can cause further injury.
- Do not inflate the cuff on the same limb which other monitoring ME EQUIPMENT is applied around simultaneously, because this could cause temporary loss of function of those simultaneously used monitoring ME EQUIPMENT.
- Using it in situations that can result in prolonged impairment of the circulation of the blood of the PATIENT.
- Do not kink the connection tube; otherwise, the cuff pressure may continuously increase, which can prevent blood flow and result in harmful injury to the PATIENT. Sensitive people, including pregnant women, pre-eclamptic patients, patients with implanted medical electronic devices; and those who have have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD), should avoid using the unit whenever possible.

♥ Recall the Records

1. Press "MEM" button to access the memory. The monitor will display the calculated value of the most recent readings first.



2. Press "MEM/UP" button or "SET/DOWN" button to rotate the history records.
 "MEM/UP" to go forward;
 "SET/DOWN" to go backward.



CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

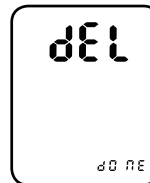
♥ Delete the Records

When you did not obtain an accurate measurement, you can clear all the results by following the steps below.

1. Under Memory Recalling Mode, press and hold both the "MEM" button and the "SET" button for 3 seconds.



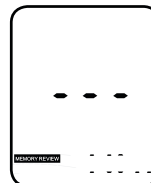
2. The LCD will display "dEL dONE", indicating that memory clearing is complete. Then it will shutdown.



CAUTION

To cancel the clearing process in Memory Recalling Mode, press "START/STOP" to turn off the monitor.

3. When there is no memory in the monitor, if you press the "MEM" button to look up history, the LCD will display as pictured to the right.



♥ Tips for Measurement

Your readings may be inaccurate if the measurement is taken in the following circumstances.



Within 1 hour
after dinner or drinking



Within 20 minutes
after taking a bath



In a very cold environment



Immediately measuring
after tea, coffee, smoking



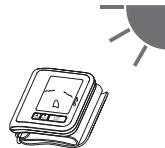
When talking or moving your fingers



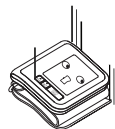
When you need to urinate

♥ Maintenance

To obtain the best performance, please follow the tips below.



Store and use in a dry place and
avoid direct sunshine



Avoid shaking and dropping.



Use a slightly damp cloth
to remove dirt.



Avoid immersing it in water.
Clean with a dry cloth if it gets wet.



Avoid a dusty environment
and unstable temperature



Avoid washing the cuff

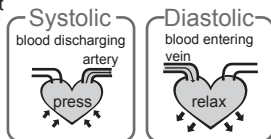


CAUTION

1. Please make sure the unit functions safely and it is in proper working conditions before use. Don't service or maintain while the device is in use.
2. If you have any problems with this device, such as setting up, maintaining or using, please contact Informed Clinical Sciences. Do not open or repair the device yourself.
3. Please report to Informed Clinical Sciences if any unexpected operation or events occur.
4. Cleaning: A dusty environment may affect the performance of the unit. Please use a soft cloth to remove the dirt from the device and cuff before and after use.
5. Calibration: The manufacturer does not require such preventive inspections or calibration by other persons and will make available on request of circuit diagrams, component part list, etc.
6. Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor's failure to power on. Please dispose of ACCESSORIES, detachable parts, and ME EQUIPMENT according to local guidelines.

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥ What is the standard blood pressure classification?

The chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

AHA Home Guideline for Upper Limit of Normal BP

SYS	135 mm Hg
DIA	85 mm Hg

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140-159	or	90-99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110



CAUTION

Please consult a physician if your result fall outside the range. Only a physician can tell whether your blood pressure value has reached a dangerous point.

♥ Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the measuring result.



CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure vary even in one day?

1. Individual blood pressure varies throughout the day. It is also affected by way you tie your cuff and your measurement position, so please take the measurement in the same position.
2. Blood pressure varies even more when you're on medication.
3. Wait at least 3 minutes to take your blood pressure again.



♥ Why are blood pressure measurements taken in the hospital different than those taken at home?

Blood pressure can vary throughout the day because of stress, foods eaten, exercise, even "white coat" syndrome at your doctor's office or in the hospital, which can make your blood pressure results higher than readings taken at home.

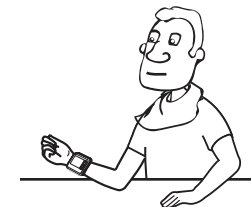
When taking your blood pressure at home, be sure to check:

- If the cuff is tied properly.
- If the cuff is too tight or too loose.
- If the cuff is tied on the wrist.
- If you feel anxious or pressured.



Tips:
Take 2 to 3 deep breaths before you begin.
Sit quietly for 4 to 5 minutes to relax before beginning.

♥ Are the results the same if measured on the right wrist?

It is OK to measure your blood pressure on both wrists; however, the results may differ. It is suggested that you measure with the same wrist each time.



This section includes a list of error messages and frequently asked questions for problems you may encounter with your pressure monitor. If the product is not operating as you think it should, check here before arranging for service.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Power is exhausted.	Charge the device
Low batteries	 Show on the display	Power is low.	Charge the device
Error message	 shows	Data communication has failed	Make sure that the phone's Bluetooth is on or within the distance range
	E 2 shows	The cuff is very tight	Refasten the cuff and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E 9 shows	Product has not been activated.	Reactivate
	E 10 or E 11 shows	The monitor detected motion while measuring.	Movement can affect the measurement. Relax for a moment and then measure again.
	E 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	Measure incorrectly.	Relax for a moment and then measure again.
	EExx, shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.

Power supply	3.7V 420mAH Built-in rechargeable lithium-ion battery, 5V / 1A USB cable
Display mode	Digital LCD V.A.46.5x36.5mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kpa-40kpa (0mmHg-300mmHg) Measurement pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg) pulse value:(40-199)beat/minute
Accuracy	Pressure: 5℃-40℃ within±0.4kpa(3mmHg) pulse value:±5%
Normal working condition	Temperature:5℃ to 40℃ Relative humidity ≤85% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃ to 60℃ RH: 10% to 93% Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of the wrist	About 13.5cm-21.5cm
Net Weight	Approx.110g
External dimensions	Approx.79.8×72.5×13.2mm
Attachment	USB cable,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22, It means the device could protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°
Software version	V01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor charged Mode: Class II ME Equipment

WARNING: No modification of this equipment is allowed.

♥ The Matched Component

1. Please use the IC SCIENCES authorized adaptor (Not Included)



Adaptor

Type: UE05WCP-050100SPC

Input: 100-240V, 50-60Hz, 0.18A

Output: 5.0V $\overline{\overline{=}}$ 1.0A

♥ Contact Information

For more information about our products, please visit www.icsciences.com.

Manufactured by: Informed Clinical Sciences Corporation

Address: 1 Joy Street, Boston, MA 02108

♥ Complied Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1: 2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	IEC 80601-2-30:2009 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	ANSI/AAMI SP10:2002/A2: 2008 Manual, electronic, or automated sphygmomanometers
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

♥ EMC Guidance

1. The Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance $d = 3,3 \text{ m}$ away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 3,3 \text{ m}$ at an IMMUNITY LEVEL of 3 V/m)